

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1438V

Filed: May 7, 2024

DEBRA HEATH,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Master Horner

*Scott William Rooney, Nemes, Rooney, P.C., Farmington Hills, MI, for petitioner.
Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for respondent.*

DECISION¹

On September 19, 2019, petitioner, Debra Heath,² filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),³ alleging that the influenza (“flu”) vaccine that petitioner received on September 20, 2016, caused her to suffer unilateral sudden sensorineural hearing loss (“SSNHL”) in her left ear. (ECF No. 1, p. 1.) For the reasons set forth below, I conclude that petitioner is *not* entitled to compensation for her SSNHL.

¹ Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² The petition was initially filed under a different surname. The caption was changed on August 15, 2022, after petitioner filed documentation of a name change. (ECF Nos. 66, 68, 71.)

³ Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient’s injury was “caused-in-fact” by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines ex rel. Sevier v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). In this case, petitioner alleges that she suffered SSNHL, which is not listed on the Vaccine Injury Table relative to any vaccine. Accordingly, petitioner must satisfy this burden of proof for a cause-in-fact claim.

The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); see *also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;” the logical sequence must be supported by “reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” *Althen*, 418 F.3d at 1278; *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based

solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the “causation-in-fact” standard, as follows:

Concisely stated, *Althen*’s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner’s causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id.* at 1279-80. That expert’s opinion must be “sound and reliable.” *Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). The *Althen* court also indicated, however, that a Program fact-finder may rely upon “circumstantial evidence,” which the court found to be consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” 481 F.3d at 1280.

II. Procedural History

Between September of 2019 and July of 2020, petitioner filed an affidavit marked as Exhibit 1, medical records marked as Exhibits 2-5, a VAERS report marked as Exhibit 6, an article about SSNHL marked as Exhibit 7, and additional medical records marked Exhibits 8-13. Respondent then filed his Rule 4 report in October of 2020. (ECF No. 34.) Respondent did not dispute that petitioner suffered an acute hearing loss beginning on November 20, 2016, but he did dispute that the flu vaccine is generally accepted as a cause of SSNHL, that any of petitioner’s physicians identified her vaccination as a cause of her hearing loss, or that the article she filed supported her burden of proof. (*Id.* at 5.)

In March of 2021, petitioner filed an expert report by otolaryngologist Hamid Djalilian, M.D. (ECF No. 40; Ex. 14 (with CV and literature marked as Tabs A-Z)). Petitioner also filed additional medical records marked as Exhibit 15 and an additional affidavit marked as Exhibit 16. (ECF Nos. 43, 46.) Thereafter respondent filed a responsive expert report by otolaryngologist Yu-Lan Mary Ying, M.D. (ECF No. 50; Exs. A-B; see also ECF No. 79 (literature marked as Tabs 1-19).) Petitioner then filed a further report by Dr. Djalilian. (ECF No. 53; Ex. 19 (with literature marked as Tabs A-O).)

On January 10, 2022, I held a Rule 5 conference. (ECF No. 55.) I raised several issues that I felt may potentially be insurmountable to petitioner and suggested she may need to consider voluntary dismissal. (*Id.*) However, petitioner filed a further report by Dr. Djalilian directly responding to my Rule 5 order. (ECF No. 61; Ex. 20 (with literature marked as Tabs A-F).) In a follow-up status conference, I advised that I intended to resolve this case on the written record pursuant to Vaccine Rule 8(d) and neither party objected. (ECF No. 63.) Respondent subsequently filed a responsive report by Dr. Ying. (ECF No. 72; Ex. C.)

Petitioner filed a motion for a ruling on the written record on March 13, 2023. (ECF No. 77.) Respondent filed his response on June 23, 2023, and petitioner later confirmed she did not wish to file any reply. (ECF Nos. 80-81.)

This case is now ripe for resolution of entitlement. I have concluded that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case without an entitlement hearing. See *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012)); see also Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

III. Factual History

a. Medical Records

Prior to the vaccination at issue, petitioner had a prior history of migraines. (See Ex. 2, p. 5; Ex. 3, p. 27.) She also had prior sinus infections. Her prior history is otherwise not germane. She had no history of hearing loss. (Ex. 2, p. 29; Ex. 11, pp. 2-8; Ex. 12, pp. 3-8.) On September 20, 2016, petitioner received the flu vaccination at issue during an annual exam with her primary care provider. (Ex. 2, p. 4.)

Twenty days after the vaccination, on October 10, 2016, petitioner was seen at the emergency department for an acute onset of left-sided hearing loss and neck pain. (Ex. 3, p. 36.) Specifically:

[P]atient states that she was at the gym earlier today[.] [S]he was doing sit ups and she states that she developed a sudden onset of pain in the left side of her neck[.] [S]he states this [happened at] about 12:30 [and] she didn't really think much of it[.] [S]he went home and went about her normal activities and at 3:00 she noticed ringing in her left ear and some hearing loss . . . [s]he has never had this happen to her before[.] [S]he has no other focal deficits [and] she is not dropping anything with her left upper extremity[.] [S]he says she feels like her ear is numb[.] [T]here is no facial droop [and] she has no nausea or vomiting[.] [S]he states that she has been dealing with some congestion[.] [S]he's been taking Advil and a decongestant but [has] been afebrile

(*Id.*) On physical exam, petitioner's left tympanic membrane⁴ showed serous otitis,⁵ but without perforation. (*Id.* at 37.) There was no external edema and no cerumen impaction.⁶ (*Id.*) Bloodwork was normal. (*Id.*) A CT of the head showed no intracranial process. A CT angiography of the head and neck showed no evidence of any significant stenosis, occlusion, dissection, or aneurysm. (*Id.*) Petitioner was noted to be neurologically intact. Despite a lack of dizziness, Meniere's⁷ was suspected. Her diagnoses were hearing loss, tinnitus,⁸ and sternocleidomastoid strain.⁹ (*Id.*)

Two days later, petitioner followed up with an Ears, Nose, Throat ("ENT") specialist. (Ex. 3, pp. 25-26.) Petitioner reported two days of hearing loss with ear fullness and muffled sound that she associated with nasal congestion, alleviated by Sudafed and Zyrtec. (*Id.* at 27.) An audiogram showed essentially normal hearing in the right ear and profound sensorineural hearing loss on the left. (*Id.* at 46.) Petitioner was diagnosed with chronic rhinitis and left-side unilateral sensorineural hearing loss. An MRI was ordered to rule out acoustic neuroma. (*Id.* at 28.) Petitioner underwent a tympanostomy and tube placement during this encounter. (*Id.*) She was prescribed steroid ear drops and oral steroids. (*Id.*) At a follow up encounter, petitioner was also

⁴ The tympanic membrane – also known as the eardrum – is "the obliquely placed, thin membranous partition between the external acoustic meatus and the tympanic cavity." *Membrana Tympanica*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=88565> (last visited May 2, 2024).

⁵ Serous otitis media is "a condition in which the air in the middle ear has been replaced by serous or mucoid fluid" as a result of inflammation of the ear. *Middle-Ear Effusion*, STEDMAN'S MEDICAL DICTIONARY (28th ed., 2006).

⁶ Cerumen impaction occurs when accumulated ear wax forms a solid mass that adheres to the wall of the external auditory canal. *Impacted Cerumen*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=64725> (last visited May 2, 2024).

⁷ Meniere's is characterized clinically by vertigo, nausea, vomiting, and tinnitus, as well as "fluctuating and progressive sensory hearing loss associated with endolymphatic hydrops." *Meniere's Disease*, STEDMAN'S MEDICAL DICTIONARY (28th ed., 2006); *see also Meniere Disease*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=30329> (last visited May 2, 2024) (defining the condition as including "hearing loss, tinnitus, and vertigo resulting from nonsuppurative disease of the labyrinth with edema").

⁸ Tinnitus is associated with the perception of a sound, such as ringing, buzzing, hissing, roaring, or clicking, in the absence of an environmental acoustic stimulus. *Tinnitus*, STEDMAN'S MEDICAL DICTIONARY (28th ed., 2006); *Tinnitus*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=50114> (last visited May 2, 2024). The condition is also associated with hearing loss. *Tinnitus*, STEDMAN'S MEDICAL DICTIONARY (28th ed., 2006).

⁹ Sternocleidomastoid strain occurs when there is an overexertion or overstretching of the sternum, clavicle, or mastoid process. *Sternocleidomastoid*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=47183> (last visited May 2, 2024); *Strain*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=47378> (last visited May 2, 2024).

recommended hyperbaric oxygen therapy, which she completed (8 sessions) between October 21 and October 31. (*Id.* at 24; Ex. 4, pp. 3-5.)

On October 25, 2016, petitioner underwent an MRI of her brain and auditory canals. (Ex. 3, p. 44.) It showed (1) “[n]onspecific white matter signal abnormality could reflect a poorly chronic ischemic change or other processes including migraine headaches. A demyelinating process is not entirely excluded” and (2) “[m]ild trapped right mastoid fluid.” The study was otherwise unremarkable. (*Id.* at 44-45.)

Petitioner returned to her ENT on November 1, 2016. (Ex. 3, pp. 19-22.) It was noted that she had not experienced any improvement and that her MRI was unremarkable. (*Id.* at 22.) Her tube was removed. (*Id.*) She was felt to have a “low probability” of hearing improvement and so amplification options were discussed. (*Id.*) Petitioner continued to pursue follow-up with respect to her treatment options, but these encounters are not informative with respect to the causation analysis below. During the course of her treatment, petitioner’s medical records never discussed the cause of her SSNHL. On January 31, 2017, petitioner completed a VAERS report. (Ex. 6.) She reported “[s]inus and head congestion for 5 days, followed by shoulder pain, tinnitus, and profound hearing loss in left ear. Diagnosed as sudden sensorineural hearing loss.” (*Id.* at 1.) Petitioner indicated the date of her adverse event was October 10, 2016. (*Id.*)

b. Petitioner’s Affidavits

In her first affidavit, petitioner stated in pertinent part that, “within 72 hours after the vaccination, I developed what appeared to be changes in my left ear, with a feeling of fullness and I also had pain in the left shoulder. That shoulder pain subsided, but the difficulties in my ear only increased.” (Ex. 1, p. 1.) She further stated that “on or about October 10, 2016, I first noticed a profound loss of hearing in the left ear while still having a feeling of fullness in the ear. I immediately went to the emergency room” (*Id.*) She indicates that “[t]hroughout the time period of September 20, 2016, until October 10, 2016, I do not recall having any cold or runny nose just the fullness in the ear.” (*Id.*) Petitioner’s second affidavit largely focuses on the extent of her injury. With regard to her initial presentation, she states that “I lost my hearing shortly after the vaccination and it changed my life instantly. . . . I went to the emergency room within hours of my symptoms.” (Ex. 16, p. 1.)

IV. Summary of Experts’ Opinions

a. Hamid Djalilian, M.D.,¹⁰ for petitioner – first report

¹⁰ Dr. Djalilian received his medical degree from the University of Minnesota Medical School, before going on to complete an internship in preliminary surgery at Hennepin County Medical Center in Minneapolis, Minnesota; a residency in otolaryngology – head and neck surgery at the University of Minnesota; and a fellowship at Minnesota Ear Head and Neck Clinic (Otology Neurology, and Skull Base Surgery). (Ex 14, Tab A, p. 1.) He is board certified in otolaryngology (head and neck surgery) and neurology. (*Id.*) He is currently employed as a professor of clinical otolaryngology and biomedical engineering, as well as the director of the Division of Neurology and Skull Base. (*Id.* at 2.) Dr. Djalilian has authored 1 book, 150

In his first report, Dr. Djalilian assesses onset of petitioner's SSNHL as occurring on October 10, 2016. (Ex. 14, p. 6.) Citing petitioner's first affidavit, he asserts that petitioner did experience her first symptom – aural fullness – within the first three days post-vaccination. (*Id.* at 5.) However, he attributes this symptom to a migraine, rather than to SSNHL. (*Id.*) Dr. Djalilian opines that petitioner first experienced a post-vaccination migraine that then later progressed to SSNHL. (*Id.* at 5-6.) He notes that a vascular cause of petitioner's SSNHL was ruled out by CT, MRI, and CT angiogram. (*Id.* at 6.)

Dr. Djalilian opines that migraine is an established adverse event following vaccination.¹¹ (Ex. 14, p. 4.) He theorizes that this phenomenon is explained by sensitivity to the egg-related protein in the flu vaccine. (*Id.* (citing A. Pradalier & J.M. Launay, *Immunological Aspects of Migraine*, 50 BIOMEDICINE & PHARMACOTHERAPY 64 (1996) (Ex. 14, Tab I); R.C. Peatfield et al., *The Prevalence of Diet-Induced Migraine*, 4 CEPHALALGIA 179 (1984) (Ex. 14, Tab J)).) “[T]he migraine process in the brain generally occurs a short time after the triggering event. It is generally not beyond a week from the event.” (*Id.* at 5.) He asserts that “[i]t is a common misconception that a migraine episode must include a headache. A silent migraine or a migraine without headache occurs in a subset of migraine patients.” (*Id.*) Further, he asserts that a subset of migraine patients present with symptoms related to the ear. (*Id.* (citing Isabella Y. Liu et al., *Bilateral Endolymphatic Hydrops in a Patient with Migraine Variant Without Vertigo: A Case Report*, 57 HEADACHE, March 2017, at 455 (Ex. 14, Tab W).) Even in the absence of headaches, he asserts that migraines are known to induce a number of disorders of the ear.¹² (*Id.* at 4.) Epidemiology supports an increased risk of

peer reviewed papers, 76 non-peer reviewed papers, 8 letters to the editor, and 44 book chapters on the subject of otolaryngology and neurology. (*Id.* at 8-34.)

¹¹ Marc Demeulemeester et al., *Rapid Safety Assessment of a Seasonal Intradermal Trivalent Influenza Vaccine*, 0 HUMAN VACCINES & IMMUNOTHERAPIES 1 (2017) (Ex. 14, Tab B); Penina Haber et al., *Post-Licensure Surveillance of Quadrivalent Live Attenuated Influenza Vaccine United States, Vaccine Adverse Event Reporting System (VAERS), July 2013-June 2014*, 33 VACCINE 1987 (2015) (Ex. 14, Tab C); Javier Diez-Domingo et al., *Safety and Tolerability of Cell Culture-Derived and Egg-Derived Trivalent Influenza Vaccines in 3 to <18-Year-Old Children and Adolescents at Risk of Influenza-Related Complications*, 49 INT'L J. INFECTIOUS DISEASE 171 (2016) (Ex. 14, Tab D); Geoffrey J. Gorse et al., *Safety and Immunogenicity of a Quadrivalent Intradermal Influenza Vaccine in Adults*, 33 VACCINE 1151 (2015) (Ex. 14, Tab E); Robert B. Belshe et al., *Comparative Immunogenicity of Trivalent Influenza Vaccine Administered by Intradermal or Intramuscular Route in Healthy Adults*, 25 VACCINE 6755 (2007) (Ex. 14, Tab F); Roger Baxter et al., *A Postmarketing Evaluation of the Safety of Ann Arbor Strain Live Attenuated Influenza Vaccine in Adults 18-49 Years of Age*, 30 VACCINE 3053 (2012) (Ex. 14, Tab G); T. M. Schurink-van't Klooster et al., *Examining a Possible Association Between Human Papilloma Virus (HPV) Vaccination and Migraine: Results of a Cohort Study in the Netherlands*, 174 EUR. J. PEDIATRICS 641 (2015) (Ex. 14, Tab H).

¹² Omid Moshtaghi et al., *Migraine-Related Aural Fullness: A Potential Clinical Entity*, 158 OTOLARYNGOLOGY–HEAD & NECK SURGERY 100 (2018) (Ex. 14, Tab K); Erik S. Viire & Robert W. Baloh, *Migraine as a Cause of Sudden Hearing Loss*, 36 HEADACHE 24 (1996) (Ex. 14, Tab L); Yildiz Arslan et al., *The Etiological Relationship Between Migraine and Sudden Hearing Loss*, 38 OTOTOLOGY & NEUROTOLOGY 1411 (2017) (Ex. 14, Tab M); Yaser Ghavami et al., *Management of Mal de Debarquement Syndrome as Vestibular Migraines*, 127 LARYNGOSCOPE 1670 (2017) (Ex. 14, Tab N); Yaser Ghavami et

hearing loss and tinnitus among migraine and headache patients.¹³ (*Id.*) Additionally, migraine medications have been shown to improve outcomes for sudden hearing loss patients. (*Id.* (citing Mehdi Abouzari et al., *Adjuvant Migraine Medications in the Treatment of Sudden Sensorineural Hearing Loss*, 131 LARYNGOSCOPE E283 (2021) (Ex. 14, Tab V)).) Dr. Djalilian theorizes that “[t]hese patients often have induction of migraine by a trigger which is thought to cause a change in blood flow in the inner ear which leads to the hearing loss and resultant tinnitus.” (*Id.* at 5 (citing Yaser Ghavami et al., *Management of Mal de Debarquement Syndrome as Vestibular Migraines*, 2016 LARYNGOSCOPE 1 (Ex. 14, Tab N); Hyung Lee et al., *Hearing Symptoms in Migrainous Infarction*, 60 ARCH NEUROL 113 (2003) (Ex. 14, Tab X)).)

Dr. Djalilian acknowledges that the causal chain he posits would be difficult to test, because only a small group of patients experience migraine-related events postvaccination and only a small percentage of migraine patients develop hearing loss. (Ex. 14, p. 5.) Moreover, the link he suggests between migraine and hearing loss “has only recently been understood” and is not widely understood among neurotology specialists. (*Id.*)

b. Yu-Lan Mary Ying, M.D.,¹⁴ for respondent – first report

Dr. Ying stresses that an identifiable cause for SSNHL will be found in only a minority of patients (between 7-45%). (Ex. A, p. 3 (citing Justin K. Chau et al., *Systematic Review of the Evidence for the Etiology of Adult Sudden Sensorineural Hearing Loss*, 120 LARYNGOSCOPE 1011 (2010) (Ex. A, Tab 4)).) For all others, the SSNHL is classified as idiopathic with the underlying etiology remaining unknown. (*Id.*

al., *Migraine Features in Patients with Meniere’s Disease*, 126 LARYNGOSCOPE 163 (2016) (Ex. 14, Tab O); Yuan F. Liu & Helen Xu, *The Intimate Relationship Between Vestibular Migraine and Meniere Disease: A Review of Pathogenesis and Presentation*, 2016 BEHAVIORAL NEUROLOGY 1 (Ex. 14, Tab P); Berthold Langguth et al., *Tinnitus and Headache*, 2015 BIOMED RES. INT’L 1 (Ex. 14, Tab Q).

¹³ So Young Kim et al., *Migraine Increases the Proportion of Sudden Sensorineural Hearing Loss: A Longitudinal Follow-Up Study*, 46 AURIS NASUS LARYNX 353 (2019) (Ex. 14, Tab S); Randolph W. Evans & Gail Ishiyama, *Migraine with Transient Unilateral Hearing Loss and Tinnitus*, 49 HEADACHE 756 (2009) (Ex. 14, Tab T); Yi-Chun Chen et al., *Risks of Tinnitus, Sensorial Hearing Impairment, and Sudden Deafness in Patients with Non-Migraine Headache*, 14 PLOS ONE 1 (2019) (Ex. 14, Tab U).

¹⁴ Dr. Ying received her medical degree from Stony Brook School of Medicine at State University of New York before going on to complete a fellowship at Howard Hughes Medical Institute – National Institute of Health in Bethesda, Maryland. (Ex. B, p. 1.) She then completed an internship in general surgery at the University of Pittsburgh Medical Center; a residency in otolaryngology with T32 Training Grant at the same institution; a fellowship in otology and neurotology at Pittsburgh Ear Associates, Allegheny General Hospital; and a fellowship in neurotology at Baylor College of Medicine in Houston, Texas. (*Id.* at 1-2.) Dr. Ling is board certified in otolaryngology and neurotology. (*Id.* at 3.) She is currently employed as an assistant professor in the Department of Otolaryngology – Head and Neck Surgery at Rutgers-New Jersey Medical School. (*Id.* at 2.) She also maintains several hospital appointments, including as an attending otolaryngologist at University Hospital in Newark, New Jersey; St. Barnabas Hospital in Livingston, New Jersey; Hackensack UMC Mountainside Hospital in Glen Ridge, New Jersey; and Hackensack University Medical Center in Hackensack, New Jersey. (*Id.*) She has authored 20 journal articles, as well as 10 reviews, invited papers, and chapters, on the subject of otolaryngology and neurotology. (*Id.* at 7-9.)

at 3-4.) Causes of SSNHL include infection, otologic disorders, trauma, and vascular, hematologic, or neoplastic causes. (*Id.*) Certain drugs may also be ototoxic. (*Id.*) Dr. Ying indicates that several viruses, including the influenza virus, have been implicated as causes of SSNHL, though the clearest causal relationship is with mumps infection, which causes deafness via endolymphatic labyrinthitis. (*Id.* at 4. (citing Chau et al., *supra*, at Ex. A, Tab 4; Martti Vuori et al., *Perceptive Deafness in Connection with Mumps: A Study of 298 Servicemen Suffering from Mumps*, 55 ACTA OTO-LARYNGOLOGICA 231 (1962) (Ex. A, Tab 5); G.A. Westmore et al., *Isolation of Mumps Virus from the Inner Ear After Sudden Deafness*, 6 BRIT. MED. J. 14 (1979) (Ex. A, Tab 6).) The incubation period for the mumps virus is 2-3 weeks. (*Id.*) Accordingly, one case report posited a causal relationship to the mumps vaccine occurring 3 weeks post-vaccination because that vaccine contains a live virus. (*Id.* (citing Masahiro Rikitake et al., *Bilateral Deafness as a Complication of the Vaccination - A Case Report*, 22 INT'L TINNITUS J. 19 (2018) (Ex. A, Tab 7)).) The flu vaccine, by contrast, does not contain any live virus. (*Id.*) Dr. Ying disputes that the available medical literature supports the flu vaccine as a cause of SSNHL. (*Id.* at 6.)

Relying on the medical records of October 10 and 12, 2016, in reference to petitioner's affidavit account of aural fullness, Dr. Ying opines that petitioner suffered onset of SSNHL about three weeks following her vaccination. (Ex. A, p. 4.) In any event, ear fullness can have many causes, including migraine, but also including sinusitis and rhinitis. (*Id.* at 5.) Moreover, Dr. Ying notes that petitioner's examination at the emergency department confirmed "some small amount of fluid" in her left ear. (*Id.*) Thus, while ear fullness can be associated with migraine, Dr. Ying opines that the presence of fluid in petitioner's ear, likely associated with her reported sinus issues, is in itself sufficient explanation for petitioner's aural fullness. (*Id.*) Petitioner's reports of an ear popping sensation, even after treatment, is consistent with Eustachian tube dysfunction from her chronic rhinitis. (*Id.*)

Dr. Ying asserts that Dr. Djalilian's theory is both novel and untestable. (Ex. A, p. 5.) Moreover, because she disagrees with his assessment of onset, she opines the timing in this case is incompatible with what Dr. Djalilian proposes, stressing that he indicated that a vaccine-related migraine event would not occur more than one-week post-vaccination. (*Id.*) Dr. Ying also stresses that there is no indication in the medical records that petitioner had a new-onset migraine condition post-vaccination and, in fact, her prior medical records indicate a prior history of migraine. (*Id.* at 6 (citing Ex. 5, p. 174; Ex. 3, p. 28).) To the extent Dr. Djalilian premises his theory on a sensitivity to egg protein, there is no indication in the medical records that petitioner has any egg allergy and she received a prior flu vaccine without issue. (*Id.* (citing Ex. 2, p. 24).) Dr. Ying opines that petitioner's own SSNHL was idiopathic. (*Id.*)

c. Dr. Djalilian's second report, responding to Dr. Ying

In response to Dr. Ying's report, Dr. Djalilian disputes that viral infection is a cause of SSNHL. Accordingly, he indicates that the question of whether the flu vaccine contains a live virus is irrelevant, because the causal relationship is unrelated to the

presence of a virus. (Ex. 19, p. 1.) Dr. Djalilian charges that Dr. Ying ignores the causal relationship between SSNHL and migraine, stressing that she does acknowledge vascular compromise as a cause of SSNHL. (*Id.*) He suggests her supporting literature is out of date. (*Id.*)

Regarding petitioner's own clinical history, Dr. Djalilian does not interpret the medical records as specifically indicating that aural fullness began on October 10. (Ex. 19, pp. 1-2.) He does not believe petitioner's affidavit contradicts the medical records and further stresses that it would not be unusual for a patient to initially ignore aural fullness on the assumption that it is attributable to congestion. (*Id.* at 2.) Regarding Dr. Ying's reference to the emergency department finding of fluid in the ear, he asserts that emergency department physicians are "notoriously poor" at identifying fluid in the middle ear and that the CT scan, which did not observe fluid in the ear, should be viewed as evidence that the exam was inaccurate. (*Id.*) He also asserts that if the fluid in the ear was attributable to sinus issues, then this also should have been observed on the CT scan. (*Id.*) Otherwise, apart from migraine, the remaining causes of ear fullness cited by Dr. Ying are irrelevant to this case, leaving migraine as the most likely cause of the ear fullness.¹⁵ (*Id.* at 2-3.)

Dr. Djalilian questions whether the pre-vaccination history of migraines is accurate. (Ex. 19, p. 3.) But in any event, regardless of whether petitioner suffered prior migraines, "[m]igraine is a genetic condition with intermittent symptoms through the patient's lifetime. Migraine episodes occur as a result of various triggers and post-vaccination activation of migraine is one of those phenomena that can trigger a migraine episode" (*Id.*) He acknowledges no migraine diagnosis was provided post-vaccination, but asserts this constitutes a missed diagnoses that would have been less likely to have been missed had petitioner been seen at a large academic medical center. (*Id.*) He asserts that petitioner's neck stiffness, pressure in the ear, facial pressure and pain, and SSNHL present a migraine etiology. (*Id.* (citing Omid Moshtaghi et al., *Migraine-Related Aural Fullness: A Potential Clinical Entity*, 158 OTOLARYNGOLOGY-HEAD & NECK SURGERY 100 (2018) (Ex. 14, Tab K); Curtis P. Schreiber et al., *Prevalence of Migraine in Patients with a History of Self-Reported or Physician-Diagnosed "Sinus" Headache*, 164 ARCH INTERN MED 1769 (2004) (Ex. 19, Tab E); Mehdi Abouzari et al., *Adjuvant Migraine Medications in the Treatment of Sudden Sensorineural Hearing Loss*, 131 LARYNGOSCOPE E283 (2021) (Ex. 14, Tab V)).)

Dr. Djalilian cites several studies that he indicates demonstrate that inflammation due to IL-1 β , IL-6, an TNF- α plays a major role in migraine pathogenesis.¹⁶ (Ex. 19, pp.

¹⁵ Dr. Djalilian also contends that it is "preposterous" for Dr. Ying to propose that petitioner, who is nearly deaf in her affected ear, can "hear" popping of the ear secondary to Eustachian tube dysfunction. (Ex. 19, p. 3.) However, this misstates Dr. Ying's opinion. Dr. Ying discussed the "sensation" of popping, not the hearing of popping. (Ex. A, p. 5.)

¹⁶ M. Yücel et al., *Serum Levels of Endocan, Claudin-5 and Cytokines in Migraine*, 20 EUR. REV. MED. & PHARMACOLOGICAL SCIS. 930 (2016) (Ex. 19, Tab F); Ibrahim Arda Yilmaz et al., *Cytokine Polymorphism in Patients with Migraine: Some Suggestive Clues of Migraine and Inflammation*, 11 PAIN MED. 492 (2010) (Ex. 19, Tab G); Todd Rozen & Sahar Z. Swidan, *Elevation of CSF Tumor Necrosis Factor α Levels in*

3-4.) TNF- α , in turn, has been shown to be an important part of the immune response to the flu vaccine. (*Id.* at 4 (citing Frédéric Bloch et al., *Production of TNF-Alpha Ex Vivo Is Predictive of an Immune Response to Flu Vaccination in a Frail Elderly Population*, 27 EURO. CYTOKINE NETWORK 63 (2016) (Ex. 19, Tab J); L. B. S. Gelinck et al., *The Effect of Anti-Tumour Necrosis Factor α Treatment on the Antibody Response to Influenza Vaccination*, 67 ANNALS RHEUMATIC DISEASES 713 (2008) (Ex. 19, Tab K)).) Dr. Djalilian also reiterated the link between egg allergy and migraines, but did not address Dr. Ying's assertion that there is no evidence petitioner had an egg allergy. (*Id.*)

d. Dr. Djalilian's third report, responding to the Rule 5 Order

In my Rule 5 Order, I noted among other issues that the records provide some evidence to support sinus congestion and fluid in the ear as possible explanations for petitioner's aural fullness whereas, especially in the absence of any report of headache, there is no indication apart from the aural fullness itself that petitioner was suffering a migraine. I noted that this likely raises an issue under *Althen* prong two. (ECF No. 55, pp. 1-2.) In response, Dr. Djalilian points out that there was no evidence of sinus infection or fluid in the ear on petitioner's CT scans. (Ex. 20, p. 1.) He cites several studies that he indicates show that migraines are often misinterpreted as sinus disease.¹⁷ (*Id.*) He reiterates the idea that aural fullness is an underrecognized symptom of migraine. (*Id.* (citing Moshtaghi et al., *supra*, at Ex. 14, Tab K; Adwight Risbud et al., *Migraine Features in Patients with Isolated Aural Fullness and Proposal for a New Diagnosis*, 42 OTOTOLOGY & NEUROTOLOGY 1580 (2021) (Ex. 20, Tab E)).)

Regarding timing, I had indicated that Dr. Djalilian would need to address the two-week gap between onset of petitioner's alleged migraine and onset of her SSNHL, and whether that period is consistent with his theory of causation. (ECF No. 55, p. 2.) Dr. Djalilian indicated that migraine can be present continuously for weeks, a type of migraine termed status migranous. (Ex. 20, p. 2 (citing Headache Classification Comm. of the Int'l Headache Society (IHS), *The International Classification of Headache Disorders, 3rd Edition (Beta Version)*, 33 CEPHALALGIA 629 (2013) (Ex. 20, Tab F) [hereinafter ICHD-3]).) He indicates that "[a]s the migraine persists, the symptoms may change and I commonly see sudden hearing loss develop in patients with chronic ear fullness." (*Id.*)

New Daily Persistent Headache and Treatment Refractory Chronic Migraine, 47 HEADACHE 1050 (2007) (Ex. 19, Tab H); Mina Abdolahi et al., *The Synergistic Effects of ω -3 Fatty Acids and Nano-Curcumin Supplementation on Tumor Necrosis Factor (TNF)- α Gene Expression and Serum Level in Migraine Patients*, 69 IMMUNOGENETICS 371 (2017) (Ex. 19, Tab I)

¹⁷ Frederick A. Godley et al., *Update on the Diagnostic Considerations for Neurogenic Nasal and Sinus Symptoms: A Current Review Suggests Adding a Possible Diagnosis of Migraine*, 40 AM. J. OTOLARYNGOLOGY 306 (2019) (Ex. 20, Tab A); Eric Eross et al., *The Sinus, Allergy and Migraine Study (SAMS)*, 47 HEADACHE 213 (2007) (Ex. 20, Tab B); Roger K. Cady & Curtis P. Schreiber, *Sinus Headache: A Clinical Conundrum*, 37 OTOLARYNGOLOGY CLINICS N. AM. 267 (2004) (Ex. 20, Tab C).

Finally, Dr. Djalilian states: “The Special Master indicates that migraine could have independently caused her sudden hearing loss. While that is true, her migraine became active only after the vaccination with the ear fullness as the first sign of this migraine activation.” (Ex. 20, p. 2.)

a. Dr. Ying’s second report

In response to Dr. Djalilian’s third report, Dr. Ying clarifies that she does not opine that petitioner was suffering a sinus infection. She opines that the fluid in the middle ear – serous otitis media – is sufficient to have caused a feeling of fullness or muffled sound in petitioner’s ear. (Ex. C, p. 1.) That serous otitis media was observed on otoscopic exam, which included a thorough description of the middle ear findings. (*Id.*) While CT temporal bone scan is the “gold standard” imaging modality for the middle ear, serous otitis media can be diagnosed based on otoscopic exam and CT scans are not typically ordered to diagnose serous otitis media. (*Id.*) In petitioner’s own case, the CT scan report was not focused on the middle ear and the radiologist did not specifically state whether the middle ear was adequately visualized. (*Id.*) Because the CT scan makes no mention of the relevant anatomy, it cannot rule out serous otitis media. (*Id.*)

In any event, even setting the serous otitis media aside, Dr. Ying does not agree that the “otologic migraine” Dr. Djalilian describes, *i.e.*, a migraine presenting only with aural fullness, has been associated with hearing loss. (Ex. C, pp. 1-2.) Several of the studies he cites, including one he conducted himself, specifically excluded patients with hearing loss from consideration for this type of migraine. (*Id.* at 2.) Thus, petitioner does not meet the definition of otologic migraine as discussed in that literature. Moreover, if hearing loss was actually a frequent finding among these patients, it should be included rather than excluded, as part of these studies. (*Id.*) Thus, Dr. Ying charges that Dr. Djalilian’s reference to his own clinical experience with aural fullness leading to hearing loss should be viewed as anecdotal only. (*Id.*)

V. Discussion

a. Findings of Fact Regarding Petitioner’s Alleged Migraine

Petitioner must prove by a preponderance of the evidence the factual circumstances surrounding her claim. § 300aa-13(a)(1)(A). Thus, before reaching a cause-in-fact analysis in this case, it is first appropriate to resolve two factual questions. First, when did the onset of petitioner’s aural fullness occur. Second, did petitioner’s aural fullness constitute a migraine.¹⁸ Absent the presence of a migraine within 72

¹⁸ “The function of a special master is not to ‘diagnose’ vaccine-related injuries, but instead to determine ‘based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]’s injury.’” *Andreu*, 569 F.3d at 1382 (quoting *Knudsen ex rel. Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). When faced with disagreement among qualified experts regarding the identification and nature of a disputed injury, the Federal Circuit has concluded that it is “appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record before applying the

hours of vaccination, petitioner has not articulated how her SSNHL could have been vaccine-caused.

i. Legal standard for fact finding

In resolving factual questions, a special master must consider the record as a whole, but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 300aa-13(b)(1). However, the Federal Circuit has held that contemporaneous medical records are ordinarily to be given significant weight due to the fact that "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Thus, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule is not absolute. Afterall, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs.*, No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." 2005 WL 6117475, at *19 (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Importantly, however, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy*, 23 Cl. Ct. at 733 (quoting the decision below).

When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the Special Master must consider the credibility of the individual offering the testimony. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. *Burns ex rel Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y Health & Human Servs.*,

Althen test to determine causation." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1351-53 (Fed. Cir. 2011).

110 Fed. Cl. 184, 204 (2013) (citing § 300aa-12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417.

i. Finding of fact regarding onset of aural fullness

The only evidence of record supporting onset of aural fullness within 72 hours of vaccination is petitioner's bare assertion within her affidavit. (Ex. 1, p. 1.) However, this assertion is not supported by either her contemporaneous medical records or her earlier VAERS submission.

In her affidavit, signed in September of 2019, petitioner states in pertinent part "within 72 hours after the vaccination, I developed what appeared to be changes in my left ear, with a feeling of fullness and I also had pain in the left shoulder. That shoulder pain subsided, but the difficulties in my ear only increased." (Ex. 1, pp. 1-2.) In addressing her October 10, 2016 emergency department encounter, she discusses only onset of "profound loss of hearing in the left ear while still having a feeling of fullness in the ear." (*Id.* at 1.) In her affidavit, petitioner does not discuss shoulder pain as any aspect of her emergency encounter. (*Id.*) She also denied any runny nose or sinus abnormalities. (*Id.*) However, in her earlier VAERS submission, submitted in January of 2017, petitioner recalled that she experienced "[s]inus and head congestion for 5 days, followed by shoulder pain, tinnitus, and profound hearing loss in the left ear." (Ex. 6, p. 1.) On this form, petitioner indicated that the date of her adverse event was October 10, 2016. (*Id.*) Thus, even setting aside the contemporaneous medical records, petitioner has not presented a consistent recollection of the onset of her symptoms.

Moreover, petitioner's recollection as stated in her earlier VAERS submission, which does not support onset of aural fullness within 72 hours of vaccination, is more consistent with her contemporaneous medical records. The contemporaneous medical record of petitioner's October 10, 2016 emergency department encounter confirms that petitioner's chief complaint included both loss of hearing and neck pain. Moreover, the record includes a detailed history. (Ex. 3, p. 36.) Like petitioner's affidavit and VAERS report, the medical record places onset of petitioner's hearing loss as arising at about the same time as her shoulder pain. (*Compare* Ex. 1, p. 1, *with* Ex. 3, p. 36.) Unlike petitioner's much later affidavit, however, the medical record clearly places the onset of all of these issues just hours prior to the emergency department encounter on October 10, 2016, about 20 days post-vaccination. (Ex. 3, p. 36.) Aural fullness was not specifically noted at this encounter. However, two days later when petitioner followed up with her ENT physician, aural fullness (specifically "ear fullness" and "sounds muffled") was reported, but only in the context of being associated with her hearing loss, which was specifically documented as having occurred two days prior. (*Id.* at 27.) Petitioner also complained of nasal congestion at both encounters and was diagnosed with rhinitis. (*Id.* at 27-28, 36.)

Considering all of this, the evidence preponderates in favor of a finding that petitioner experienced onset of neck pain and hearing loss with associated aural

fullness on October 10, 2016. Prior to that, petitioner experienced a period of nasal or sinus congestion lasting for about five days. Thus, even petitioner's nasal congestion is not evidenced prior to about October 5, 2016, some two weeks post-vaccination.

ii. Finding of fact regarding the presence of a post-vaccination migraine

Petitioner never reported to her physicians that she was suffering a migraine or any form of headache pain post-vaccination. Nor was she diagnosed with a migraine at that time. However, petitioner's expert opines that headache is not a required feature of migraine and that her reported aural fullness should be interpreted as constituting a migraine. (Ex. 14, p. 5; Ex. 20, p. 1.) Both parties' experts agree that aural fullness can be a symptom of a migraine (Ex. 19, p. 3; Ex A, p. 5); however, they also agree that migraine is only one of many causes of aural fullness (Ex. 19, pp. 2-3; Ex. A, p. 5). Both the medical records and respondent's expert point to other causes of aural fullness being implicated in this case.

First, the evidence preponderates in favor of a finding that petitioner had fluid in her middle ear as observed by her examining physician during her first emergency department encounter. Whereas Dr. Djalilian contends an emergency department physician's assessment of the inner ear should not be trusted, Dr. Ying stresses that the documented exam was thorough, casting doubt on the suggestion it should be reflexively rejected. (*Compare* Ex. 19, p. 2, *with* Ex. C, p. 1.) Dr. Djalilian cites a study that found a 4-21% variability in the clinical diagnosis of otitis media; however, he overstates by suggesting that the study demonstrated over-diagnosis in particular. (Ex. 19, p. 2 (citing Joseph L. Lyon et al., *Variation in the Diagnosis of Upper Respiratory Tract Infections and Otitis Media in an Urgent Medical Care Practice*, 7 ARCH FAM MED 249 (1998) (Ex. 19, Tab A)).) But in any event, even if the diagnostic variability observed in the study is less than ideal, the degree of variability identified in the study still suggests that only a minority of patients are at risk of misdiagnosis. Additionally, whereas Dr. Djalilian questions why the fluid was not detected on CT scan, Dr. Ying points out that the CT scans in this case do not confirm review of the middle ear. (*Compare id.*, *with* Ex. C, p. 1.) Dr. Djalilian is therefore not persuasive in seeking to discount the presence of this finding. Although Dr. Djalilian disagrees as to the presence of any middle ear fluid, he has not disputed that middle ear fluid can explain aural fullness.

Second, Dr. Ying further opines that the fluid in the inner ear may likely be associated with petitioner's otherwise documented sinus congestion. (Ex. A, p. 5.) Moreover, sinus congestion itself can be associated with aural fullness. (*Id.*) Although Dr. Ying disclaims any opinion that petitioner's reported congestion constituted a sinus infection (Ex. C, p. 1), petitioner's medical records clearly and consistently document that she was experiencing congestion at the time of her reported aural fullness (Ex. 3, pp. 27, 36). In fact, petitioner specifically reported to her ENT physician that her symptoms had been alleviated by Sudafed and he diagnosed chronic rhinitis. (*Id.* at 27-28.) As discussed above, petitioner's affidavit, signed in September of 2019, disclaims

any recollection that she was experiencing any cold or runny nose between her vaccination and onset of SSNHL (Ex. 1, p. 1); however, her much earlier VAERS report from January of 2017, specifically recalls that she experienced five days of sinus and head congestion prior to onset of her hearing loss (Ex. 6, p. 1). Dr. Djalilian cites several articles for the proposition that sinus symptoms should be reinterpreted as manifestations of migraine. (Ex. 20, p. 1.) However, these articles merely address whether headache pain should be viewed as more likely due to migraine, even when occurring in the presence of sinus congestion. Nothing in the cited papers suggests that sinus or nasal congestion are symptoms of migraine or could be construed as evidence of a migraine, and petitioner did not report having any headache pain.

Nonetheless, Dr. Djalilian cites two papers from 2018 and 2021 proposing that aural fullness, even in isolation, should constitute a new diagnostic entity for migraine – an “otologic migraine.” (Ex. 20, p. 1 (citing Moshtaghi et al., *supra*, at Ex. 14, Tab K; Risbud et al., *supra*, at Ex. 20, Tab E).) However, these papers make clear that this is a proposed, rather than accepted, clinical entity. As the International Classification of Headache Disorders filed by petitioner makes clear, migraine is first and foremost a headache disorder (ICHD-3, *supra*, at Ex. 20, Tab F, p. 16)), whereas this petitioner did not have any headache. The two papers cited by Dr. Djalilian explain that many of the subjects do not meet all of the current diagnostic criteria for migraine. (Moshtaghi et al., *supra*, at Ex. 14, Tab K, pp. 2-3; Risbud et al., *supra*, at Ex. 20, Tab E, p. 2.) However, it does appear that all of the subjects had some indicators of migraine beyond aural fullness. Moreover, these two papers support only the possibility that migraine may be considered a cause of aural fullness as an etiology of exclusion. (Moshtaghi et al., *supra*, at Ex. 14, Tab K, p. 1 (“Patients with isolated persistent [aural fullness] for 6 months or more were included with all possible etiologies ruled out.”); Risbud et al., *supra*, at Ex. 20, Tab E, p. 1 (defining migraine-related aural fullness as “isolated, prolonged aural fullness concurrent with migraine features once other etiologies were ruled out . . .”)) Here, however, petitioner has more likely explanations for her aural fullness as discussed above.

In any event, given that the onset of aural fullness occurred with the onset of SSNHL as discussed above, it must also be noted that aural fullness can be a symptom of the SSNHL itself, regardless of any sinus congestion or middle ear fluid. (*E.g.* Chau et al., *supra*, at Ex. A, Tab 4, p. 3.) In that regard, Dr. Ying is persuasive in stressing that Dr. Djalilian’s own studies excluded individuals with hearing loss from classification of otologic migraine and for good reason. Thus, even if accepting otologic migraine as a valid clinical entity, petitioner still does not fit into that conceptualization. Moreover, even if petitioner could possibly be diagnosed as suffering otologic migraine, that is still a far less likely explanation for her condition as compared to the other possible causes of aural fullness evidenced in this case.

Considering all of this, there is not preponderant evidence that petitioner suffered any migraine at all during the weeks following the vaccination at issue in this case.

b. Causation-in-Fact

As noted above, petitioner's theory of causation is premised on the presence of a migraine (evidenced by aural fullness) within 72 hours of vaccination. Accordingly, the above-discussed findings of fact are fatal to petitioner's claim. Therefore, it is not necessary to do a complete *Althen* analysis.¹⁹ Below, I will briefly explain why petitioner has not demonstrated vaccine causation under *Althen* prongs two and three. Although I remain skeptical of petitioner's theory of causation, it is not necessary to separately address *Althen* prong one.²⁰ Even accepting Dr. Djalilian's theory *arguendo* as a matter of general causation, petitioner has failed to demonstrate specific causation under the facts of this case.

i. *Althen* Prong Two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant*, 956 F.2d at 1148. Medical records are generally viewed as particularly trustworthy evidence. *Cucuras*, 993 F.2d at 1528. However, medical records and/or statements of a treating physician's views do not *per se* bind the special master. See § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special

¹⁹ In her motion for a ruling on the record, petitioner titles her arguments as pertaining to either the *Althen* test for causation-in-fact or the overlapping aspects of the *Loving* test for significant aggravation (*i.e.*, *Loving* prongs four through six). (ECF No. 77, pp. 17-22.) However, petitioner has not actually articulated any significant aggravation argument. Nor did petitioner address the first three *Loving* prongs. Notably, respondent has stressed that petitioner had a prior history of migraines. That fact could conceivably implicate a significant aggravation analysis, given the nature of Dr. Djalilian's opinion. However, my above finding that petitioner did not experience a migraine post-vaccination would be fatal to such a claim under any analysis of the first three *Loving* prongs.

²⁰ In one prior ruling, I found a petitioner entitled to compensation for SSNHL caused by the flu vaccine based on a "stress response" theory of causation. *Madigan v. Sec'y of Health & Human Servs.*, No. 14-1187V, 2021 WL 3046614 (Fed. Cl. Spec. Mstr. June 25, 2021). A significant factor in that analysis, however, was that respondent's expert had not challenged the immunologic aspects of the stress response theory as an explanation for SSNHL. *Id.* at *13. A subsequent decision distinguished *Madigan* with respect to the viability of that theory. *M.R. v. Sec'y of Health & Human Servs.*, No. 16-1024V, 2023 WL 4936727, at *27 (Fed. Cl. Spec. Mstr. June 30, 2023). In any event, petitioner in this case has not advanced the stress response theory. Several other prior cases have otherwise determined that SSNHL was not vaccine-caused. *Doe/16 v. Sec'y of Health & Human Servs.*, No. 06-670V, 2008 WL 2390064 (Fed. Cl. Spec. Mstr. June 2, 2008); *Inamdar v. Sec'y of Health & Human Servs.*, No. 15-1173V, 2019 WL 1160341 (Fed. Cl. Spec. Mstr. Feb. 8, 2019); *Kelly v. Sec'y of Health & Human Servs.*, No. 16-878V, 2021 WL 5276373 (Fed. Cl. Spec. Mstr. Oct. 18, 2021), *motion for review denied*, 160 Fed. Cl. 316 (2022); *Alsaadeh v. Sec'y of Health & Human Servs.*, No. 19-1097V, 2024 WL 694072 (Fed. Cl. Spec. Mstr. Jan. 23, 2024); *Herms v. Sec'y of Health & Human Servs.*, No. 19-70V, 2024 WL 1340669 (Fed. Cl. Spec. Mstr. Mar. 4, 2024). Thus, program history as a whole suggests that petitioners face difficulty seeking to establish that SSNHL can be vaccine-caused. In this particular case, the theory is further attenuated. Petitioner seeks to establish that vaccine can cause migraine and that migraine can, in turn, cause SSNHL.

master or court”); *Snyder ex rel. Snyder v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009) (“[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted.”). A petitioner may support a cause-in-fact claim through either medical records or expert medical opinion. § 300aa-13(a). The special master is required to consider all the relevant evidence of record, draw plausible inferences and articulate a rational basis for the decision. *Winkler v. Sec’y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines*, 940 F.2d at 1528).

In her motion for a ruling on the written record, petitioner concedes that her medical records support neither her alleged timing of onset nor her proposed causal relationship between vaccination and injury. (ECF No. 77, pp. 20-21.) She focuses instead on (1) the idea that the flu vaccine has been shown to cause increased incidences of headache and (2) that migraine sufferers being at increased risk of hearing loss. (*Id.* at 20.) She asserts that her expert’s explanation supports this as a logical sequence of cause and effect vis-à-vis the initial timing of petitioner’s alleged migraine. (*Id.* at 21.)

Petitioner’s expert’s opinion is premised on assumptions that are not preponderantly supported. Specifically, for the reasons discussed above, petitioner did not experience aural fullness within 72 hours of vaccination and her aural fullness is unlikely to constitute a migraine. Accordingly, Dr. Djalilian’s opinion does not carry petitioner’s burden of proof with respect to demonstrating a logical sequence of cause and effect implicating petitioner’s vaccine as a cause of her injury. *Burns*, 3 F.3d at 417 (holding that “[t]he special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner’s medical expert.”); *see also Rickett v. Sec’y of Health & Human Servs.*, 468 F. App’x 952, 958 (Fed. Cir. 2011) (holding that “it was not error for the Special Master to assign less weight to Dr. Bellanti’s conclusion regarding challenge-rechallenge to the extent it hinged upon Mr. Rickett’s testimony that was inconsistent with the medical records”); *Dobrydnev v. Sec’y of Health & Human Servs.*, 566 F. App’x 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that “[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert’s opinion”) (alteration in original) (quoting *Dobrydneva v. Sec’y of Health & Human Servs.*, No. 04-1593V, 2010 WL 8106881 (Fed. Cl. Spec. Mstr. Oct. 27, 2010), *rev’d sub nom. Dobrydnev v. Sec’y of Health & Human Servs.*, 98 Fed. Cl. 190 (2011), *rev’d*, 566 F. App’x 976 (Fed. Cir. 2014)) (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993))); *Bushnell v. Sec’y of Health & Human Servs.*, No. 02-1648V, 2015 WL 4099824, at *12 (Fed. Cl. Spec. Mstr. June 12, 2015) (finding that “because Dr. Marks’ opinion is based on a false assumption regarding the onset of J.R.B.’s condition, and the incorrect assumption of a ‘stepwise regression’ after each vaccine administration, it should not be credited”). Absent these unsupported assumptions, Dr. Djalilian has not otherwise articulated any causal opinion that would support petitioner’s flu vaccine as the cause of SSNHL occurring 20 days post-vaccination.

Additionally, in my Rule 5 Order, I prompted petitioner to have Dr. Djalilian address whether onset of SSNHL occurring two weeks after the initial onset of a migraine is consistent with what he has theorized. (ECF No. 55, p. 2.) I noted that the case reports he has relied upon of hearing loss among migraine sufferers (which do not even implicate any vaccination) involved instances of SSNHL occurring at the same time as migraine onset. (*Id.* (citing Randolph W. Evans & Gail Ishiyama, *Migraine with Transient Unilateral Hearing Loss and Tinnitus*, 49 HEADACHE 756 (2009) (Ex. 14, Tab T); Lee et al., *supra*, at Ex. 14, Tab X).) Co-occurring migraine and hearing loss appears to be more consistent with the mechanism Dr. Djalilian has proposed. He opines that vaccination may trigger a migraine via an inflammatory response and, further, that that “[t]hese patients often have induction of migraine by a trigger which is thought to cause a change in blood flow in the inner ear which leads to the hearing loss and resultant tinnitus.” (Ex. 14, p. 5 (citing Ghavami et al., *supra*, at Ex. 14, Tab N; Lee et al., *supra*, at Ex. 14, Tab X).) Even after having been provided an opportunity to address this issue, Dr. Djalilian has not articulated any basis for supposing that an inflammatory response to vaccination would trigger aural fullness and migraine within three days of vaccination and then, only after fourteen more days, go on to trigger a change in blood flow within the ear leading to sudden hearing loss. His only response to my Rule 5 Order was to state that he has personally witnessed patients with chronic aural fullness later suffer sudden hearing loss. (Ex. 20, p. 1.) However, even if crediting this anecdotal personal experience, it reveals nothing of the actual relationship between the aural fullness and hearing loss or whether any other trigger was implicated for the hearing loss. Demonstrating that migraine sufferers are prone to hearing loss does not establish a logical sequence of cause and effect that could implicate petitioner’s vaccine as a cause of her condition. Indeed, in his final report, Dr. Djalilian explicitly opined that migraine alone could independently cause petitioner’s hearing loss (*Id.* at 2) and petitioner otherwise had a history of migraines (See Ex. 2, p. 5; Ex. 3, p. 27). Thus, Dr. Djalilian’s opinion would be flawed, even if his factual assumptions were preponderantly supported.

ii. Althen Prong Three

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.*; *Shapiro v. Sec’y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *reconsideration denied after remand*, 105 Fed. Cl. 353 (2012), *aff’d per curiam*, 503 F. App’x 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877, at *26 (Fed. Cl. Spec. Mstr. May 30, 2013), *motion for review denied sub nom. C.K. v. Sec’y of Health &*

Human Servs., 113 Fed. Cl. 757 (2013), *aff'd sub nom. Koehn v. Sec'y of Health & Human Servs.*, 773 F.3d 1239 (Fed. Cir. 2014).

In her motion for a ruling on the written record, petitioner argues (1) that “the six month timeframe for the onset of non-specific reactions to a vaccine has been accepted” by the court²¹ and (2) that “[l]ikewise, Courts have found that ‘vaccine associated antibody-mediated adverse events occur within four to six weeks (42 days) of immunization.’” (ECF No. 77, p. 21 (quoting *Phillips v. Sec'y of Health & Human Servs.*, No. 16-906V, 2020 WL 7767511, at *30 (Fed. Cl. Spec. Mstr. Nov. 23, 2020)).) However, these are not the mechanisms of injury implicated by her expert’s theory of causation. Instead, petitioner acknowledges that “[t]he migraine process in the brain generally occurs a short time after the triggering event. It is generally not beyond a week from the event. The time between the triggering event and the occurrence of the migraine event is variable in patients and can be between an hour and a few days depending on the trigger.” (*Id.* at 22; see also Ex. 14, p. 5.) Thus, Dr. Djalilian specifically premised his causal assessment on an onset of migraine (evidenced by aural fullness) occurring within 72 hours of vaccination. (Ex. 14, p. 5.)

Because I have found both that petitioner did not experience any migraine at all, and further that the symptom of aural fullness did not begin until October 10, 2016, this is fatal to petitioner’s showing under *Althen* prong three. Dr. Djalilian has not articulated any causal opinion that would indicate that SSNHL occurring 20 days post-vaccination could be vaccine-caused.

VI. Conclusion

Petitioner has clearly suffered and for that she has my sympathy. However, for all the reasons discussed above, petitioner has not met her burden of proof necessary to demonstrate that her condition was vaccine-caused. Accordingly, this case is dismissed.²²

IT IS SO ORDERED.

s/Daniel T. Horner

Daniel T. Horner
Special Master

²¹ For this proposition, petitioner cites *Morgan v. Secretary of Health & Human Services*, No. 13-529V, 2015 WL 9694667 (Fed. Cl. Spec. Mstr. Dec. 10, 2015). However, petitioner misreads the decision. Although petitioner is correct that one of the experts in the case opined that a six-month onset is appropriate for onset of a non-specific reaction to a vaccine, that is not what was accepted in the case. *Id.* at *8, 15. The special master found that onset of ulcerative colitis beginning within one week of vaccination was consistent with the petitioner’s theory of causation, which was based on a T-cell mediated immune response. *Id.* at *15.

²² In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.